COVIDIEN

510(k) Summary

APR 2 8 2014

Date: April 28, 2014

510(k) Submitter/Holder

Covidien llc
15 Hampshire Street
Mansfield, MA 02048

Contact

Heather V. Nigro
Senior Director, Global Regulatory Affairs
Telephone: 508-452-1936
Fax: 508-452-1941
Email: heather.nigro@covidien.com

Name of Device

Trade Name:	Emprint™ Ablation System
Common Name:	Microwave ablation system and accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, class II, NEY).

Purpose of Submission

The purpose of this submission is to gain clearance for a new microwave ablation system.

Predicate Devices

Emprint™ Ablation System described in this submission is substantially equivalent to the following commercially available predicate devices:

Trade Name:	Valleylab Microwave Ablation Generator
Device Common Name:	Microwave ablation system and accessories
510(k) Number:	K072687
Manufacturer:	Covidien llc
Trade Name:	Certus 140 2.45 GHz Ablation System and Accessories
Device Common Name:	Microwave ablation system and accessories
510(k) Number:	K113237
Manufacturer:	NeuWave Medical, Inc.

System Description

The Emprint™ Ablation System is a microwave-based system intended to deliver energy through an antenna inserted into soft tissue for the purpose of coagulating (ablating) a defined volume of that tissue. The Emprint™ Ablation System utilizes a 2450 MHz 100W generator to deliver power to a single microwave ablation antenna.

The Emprint™ Ablation Generator is composed of analog and digital circuits with no software or firmware. The Emprint™ Ablation Generator provides for user setting of ablation time and ablation power (5 to 100W). With an optional temperature probe, the Emprint™

Ablation Generator can be set to monitor the temperature of a desired target and to automatically shut the generator off when the target reaches a pre-set temperature.

The Emprint™ Ablation System uses circulating room temperature normal saline to cool the non-radiating portion of the antenna shaft and to provide a more consistent ablation zone. The normal saline is pumped from an IV bag through the antenna shaft and back to the IV bag in a closed system. No saline is in contact with the patient.

The Emprint™ Ablation System consists of the following components: Emprint™ Ablation Generator (2450 MHz), Emprint™ Ablation Antenna (sterile, single use), Emprint™ Ablation Reusable Cable, and Emprint™ Ablation Pump. The system also includes the following optional components: Emprint™ Ablation Cart (with Isolation Transformer), Remote Temperature Probe (sterile, single-use), and Footswitch.

The system must be used with a standard IV bag of sterile normal saline (not provided with the system).

Intended Use

The Covidien Emprint™ Ablation System is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors.

The Covidien Emprint™ Ablation System is not intended for use in cardiac procedures.

Technological Characteristics

The Emprint™ Ablation System operates at 2,450 MHz and is capable of operating up to 100 Watts. The user has the ability to select the desired power and time limits. The substantial equivalence of the Emprint™ Ablation System to the predicates is shown by similarity in intended use, indications for use, materials, and performance.

Performance Data

The performance of the proposed device was characterized using the same methods used for one of the predicate devices. Coagulations were conducted on several ex vivo and in vivo tissue types at various power and duration settings. The shapes of the coagulation zones created were analyzed and compared to that of the predicate. Bench testing also included verification of dimensional characteristics, surface temperatures, and skin penetration.

The system adheres to the applicable IEC 60601 standards.

Sterilization

The Emprint™ Ablation Generator, the Reusable Cable, the Pump, and the Cart are not provided sterile and are not used in the sterile field. These four components are reusable, and their cleaning instructions are provided in the instructions for use.

Sterilization validation was performed on the packaged Ablation Antenna and the Remote Temperature Probe according to the requirements of ISO 11135-1: 2007 *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*. The sterility assurance level for the devices is 10^{-6}.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 28, 2014

Covidien LLC
Ms. Heather Nigro
Senior Director, Global Regulatory Affairs
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K133821
Trade/Device Name: Emprint Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Microwave Ablation System And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: March 27, 2014
Received: March 28, 2014

Dear Ms. Nigro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K133821

Device Name: Emprint™ Ablation System

Indications for Use:

The Covidien Emprint™ Ablation System is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors.

The Covidien Emprint™ Ablation System is not intended for use in cardiac procedures.

Prescription Use (Part 21 CFR 801 Subpart D)	✓	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S